DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alliance Medical Corporation
c/o Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, AZ 85044

NOV 1 2004

Re: K012708 - Supplemental Validation Submission
Trade Name: See Enclosed List
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: NLH
Dated: August 14, 2001
Received: August 14, 2001

Dear Ms. Barton:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on August 13, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Enclosure – List of Devices

Orig models found to be SE
Bard (55)
006245
008567
200060
200066
200067
200069
200151
200202
200203
200472
200473
200573
200574
200578
200580
200581
200583
200584
200591
200594
200596
200597
200624
200719
200792
400001
400004
400005
400006
400007
400008
400011
400012
400014
400016
400017
400023
400035

Orig models found to be SE
400044
400045
400046
400047
400048
400071
400099
400100
500202
500203
006245P
200060E
200588E
5FVS00010
6FMC00098
6FMC00518
6FMC00687
Cordis Webster (68)
D5-08D-P10-FS
D5S-06AL-252-MS
D5S-06AL-252-RT
D5S-AL-252-PS
D6-06DR-002-FS
D6-06DR-002-RT
D6-06DR-005-FS
D6-08DR-002-FS
D6-08DR-002-RT
D6-10DR-P10-FS
D6-10DR-P10-RT
D6-10FR-005-FS
D6-AG-252-PS
D6-AL-252-PS
D6-BL-252-PS
D6-DG-252-PS
D6-DL-252-PS
D6-DR-005-PS
D6-DR-010-PS
D6-DR-252-PS
D6S-08DR-PRY-FS
D6S-270L-252-PS
D7-06DL-002-FS

Orig models found to be SE
D7-06DL-002-TS
D7-06DR-002-TS
D7-08DL-002-FS
D7-08DL-002-RT
D7-08DR-002-FS
D7-08DR-002-RT
D7-08DR-005-FS
D7-08R-HIS-FS
D7-10DR-P10-FS
D7-10DR-P10-RT
D7-10FR-010-FS
D7-270L-252-PS
D7-270RL-252-PS
D7-A20-131-FS
D7-AG-252-PS
D7-AL-252-PS
D7-BG-252-PS
D7-BL-252-PS
D7-CG-252-PS
D7-CL-252-PS
D7-DG-252-PS
D7-DL-005-PS
D7-DL-252-PS
D7-DR-005-PS
D7-DR-010-PS
D7-DR-252-PS
D7-EG-252-PS
D7-EL-252-PS
D7-FG-252-PS
D7-FL-252-PS
D7-PSL-252-PS
D7R-20-P14-FS
D7-T20-282-FS
D7-T20-P15-FS
D8BR-BG-252-PS
D8BR-BL-252-PS
D8BR-DG-252-PS
D8BR-DL-252-PS
D8BR-FL-252-PS
D8-CG-252-PS
D8-DG-252-PS

Orig models found to be SE
D8-DL-252-PS
D8-FG-252-PS
OD7-3X4D-010-FS
OD7-8X2D-005-FS
Daig (29)
401430
401434
401435
401436
401440
401441
401442
401443
401444
401445
401449
401450
401451
401453
401466
401474
401475
401528
401860
401863
401864
401872
401873
401876
401878
401890
401891
401894
401904
EPT (23)
5291
5291S
5292
5292S
5294
5294S

Orig models found to be SE
5298S
5404S
5414S
5418
5420
5429
5433
5434
5457
5458
5470
5472
5481
5482
5491
5563
5920
Medtronic (9)
041002JM
041002UM
041005DM
041005JM
041005UM
04122JM
04125JM
04125UM
044216J

2. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number: K012708
(if known)

Device Name: Electrophysiology (EP) Catheter

Sponsor Name: Alliance Medical Corporation

Indications for Use:

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012708
EMallin

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ____

PART C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter

Alliance Medical Corporation
10232 51st Street
Phoenix, Arizona 85044

2. Contact Person

Don Selvey
Vice President, Regulatory Affairs & Quality Assurance
Alliance Medical Corporation
(480) 763-5300 – Telephone
(480) 763-5310 – Facsimile
dselvey@reprocessing.com

3. Device Name

a. Trade or Proprietary Name

Electrophysiology Catheter

b. Common Name, Usual or Classification Name

Electrode recording catheter

4. Predicate Devices

Bard	Cordis Webster*	Daig**	EP Technologies	Medtronic
K891908	K892265	K914278	K913375	K931794
K904080	K953663	K942379	K924108	K951347
K912213	K953678	K002976	K924109	K953185
K921872	K955817		K924163	K964272
K971265	K991531		K940167	K981642
	K992965		K940168	
	K002333		K003452	

*The Celsius/CelsiusII diagnostic catheters were approved under PMA P950005.
**The Livewire diagnostic catheter was approved under PMA P960016.

5. Description of the Device

Diagnostic Electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation.

EP catheter designs all incorporate a connector, a handpiece, a flexible polymeric shaft, and a distal tip containing two or more electrodes. The distal tips of steerable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

6. Intended Use of the Device

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

7. Comparison of the Technological Features of the Reprocessed and Original Devices

Diagnostic catheters are available in various configurations. Key parameters include the size of the tip, number of electrodes, length, curve of the tip, and whether or not the tip is deflectable. Since reprocessing does not significantly change any of these parameters, the reprocessed catheters are the same as the original devices.